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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,585	03/30/2001	Lino R. Becerra	MGH-004BUS	1273
21559	7590	01/29/2004		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER SHAW, SHAWNA JEANNINE	
			ART UNIT 3737	PAPER NUMBER 17

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/822,585

Applicant(s)

BECERRA ET AL. *or*

Examiner

Shawna J. Shaw

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 19-23, 27-30 and 39-44 is/are rejected.
- 7) ☒ Claim(s) 11-18 and 24-26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The references listed in the IDS filed 9/20/01 have been found in application 09/729,665, however the examiner notes that the PTO form 1449 is missing dates for some of the references. The examiner requests that applicants supply the month and year of publication for these references - particularly where common inventors are involved.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a) because they fail to show elements 100, 118 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claims 1, 39, 41, 42 and 44 are objected to because of the following informalities: Claims 1, 39 and 41 appear to be incomplete in that the step of applying a stimulus is not set forth and the correlating step requires correlation with physiological and psychophysical data. The examiner suggests combining these claims with the experimental process of claim 22. Claims 42 and 44 appear incomplete in that they are

drawn to a method for evaluating the efficacy of a treatment for pain, however do not set forth a corresponding step. The examiner suggests inserting –to determine efficacy of the treatment—after “comparing the first and second patterns.” Claims 42 and 44 are further incomplete in that the correlating step requires correlation with physiological and psychophysical data. The phrase “from the same at least two different” in claim 42 line 6 is also confusing. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not teach how to correlate signals in a reward/aversion region to a type of pain absent an applied stimulus.

Claims 1, 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The step of applying a defined stimulus which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The correlating and interpreting/measuring steps cannot be successfully performed without a defined pain stimulus.

Claims 42 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not teach how to correlate the effect of a drug to a reward/aversion region of the brain absent physiological and psychophysical data (see specification p. 110 lines 21-25).

Claims 42 and 44 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The step of applying a defined stimulus which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The efficacy of a treatment cannot be determined absent correlation with physiological and psychophysical data (see specification p. 110 lines 21-25).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-10, 19, 20, 22, 27 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Becerra et al. "Human Brain Activation Under Controlled Thermal Stimulation and Habituation to Noxious Heat: An fMRI Study" of record.

Becerra et al. teaches obtaining fMRI signals of CNS activity in response to “non-significantly painful” stimuli (i.e., 41°C) and “painful” stimuli (i.e., 46°C). Becerra et al. further teach localizing signals to specific anatomical and functional CNS regions which participate in reward/aversion functions, and correlating and interpreting the signals in the regions to a “type” of pain such as acute pain vs. “non-significant” pain or discriminatory vs., motivational pain, etc. (see “Discussion”). Moreover, Becerra et al. discloses transforming the signals into Talairach coordinates and creating statistical maps as well as quantitating (e.g., by volume or intensity), and calculating percent signal change of a ROI with respect to a known threshold. See Tables 1-3 and Figures 4, 6 and 8.

Claims 1-10, 22, 28, 29 and 39-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Wu et al. “Central Nervous Pathway for Acupuncture Stimulation: Localization of Processing with Functional MR Imaging of the Brain – Preliminary Experience” of record.

Wu et al. teaches a method for correlating and mapping signals in a reward/aversion brain region, such as the NAc, to a “type” of pain (e.g., low intensity - high intensity, real acupuncture vs. perceived acupuncture) in conjunction with treatment such as acupuncture. In addition, Wu et al. further assesses psychophysical and physiological responses from the subject under study. Moreover, Wu et al. discloses transforming the signals into Talairach coordinates and creating statistical

maps as well as calculating percent signal change of a ROI with respect to a known threshold. See pp. 135-138.

Claims 1-10, 22, 27, 39 and 40 are rejected under 35 U.S.C. 102(a) as being anticipated by Tolle et al. "Region-Specific Encoding of Sensory and Affective Components of Pain in the Human Brain: A Positron Emission Tomography Correlation Analysis" of record.

Tolle et al. teaches a method for correlating and mapping signals in a reward/aversion brain region to a "type" of pain (i.e., pain threshold, pain intensity, pain unpleasantness). Moreover, Tolle et al. discloses transforming the signals into Talairach coordinates and creating statistical maps as well as quantitating signals for comparison. See 931-945. See fig. 3 and pp. 40-45.

Claims 1-10, 19, 20, 22, 23, 30, 39 and 40 are rejected under 35 U.S.C. 102(a) as being anticipated by Iadarola "Neural activation during acute capsaicin-evoked pain and allodynia assessed with PET" of record.

Iadarola et al. teaches a method for correlating and mapping signals in a reward/aversion brain region to a "type" of pain (e.g., light brush, capsaicin, allodynia). Moreover, Iadarola et al. discloses transforming the signals into Talairach coordinates and creating statistical maps as well as quantitating signals for comparison. See 931-945.

***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Becerra et al. ("Human Brain Activation"), Wu et al. ("Central Nervous Pathway"), Tolle et al. ("Region-Specific Encoding") or Iadarola ("Neural activation") of record in view of Sodickson.

Regarding claim 21, Becerra et al., Wu et al., Tolle et al., and Iadarola differ from the claimed invention in that a neural network processor is not explicitly addressed. Sodickson provides the general teaching of a neural network processor to analyze digital image data (col. 17 lines 25-30). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to utilize a neural network



processor as taught by Sodickson in the invention as taught by Becerra et al., Wu et al., Tolle et al., or Iadonola to provide a faster and more accurate means for processing minute variations in, and voluminous amounts of, digital images.

### ***Allowable Subject Matter***

Claims 11-18 and 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-10, 19-23 and 27-30 have been considered but are moot in view of the new ground(s) of rejection.

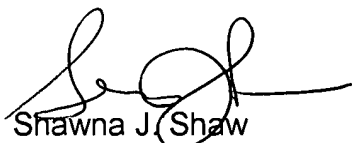
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'Shawna J. Shaw', with a stylized, looping flourish extending to the right.

Shawna J. Shaw  
Primary Examiner  
1/22/04